Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Energy and Commerce
Hearing on "Examining Drug Shortages and Recent Efforts to Address Them"
February 10, 2014

(As Prepared for Delivery)

In recent years, we have seen a dramatic increase in the number of drug shortages in the United States, particularly with generic sterile injectable drugs.

While the number of new shortages dipped in 2012 and 2013, the total number of ongoing shortages has continued to increase. This is unacceptable. Numerous drugs have remained on FDA's shortage list for some time. What is the agency doing to help address these situations?

Recent news reports have highlighted shortages of oncology products, parenteral nutrition products, and even common, yet critically important saline solutions.

Such shortages lead to delays in treatment, rationing of care, and higher costs. They can also pose greater risk to patients in the form of medication errors and as providers are forced to seek alternative treatments.

Drug shortages are a very challenging problem and it is clear that there is no simple solution. We recognize the complicated nature of this issue as well as the severity. Last Congress, the subcommittee took action by including a section on drug shortages in the Food and Drug Administration Safety and Innovation Act (FDASIA), which was signed into law on July 9, 2012.

Title X of FDASIA sought to address drug shortages by giving new authorities and responsibilities to the Food and Drug Administration and placing expanded requirements on drug manufacturers to notify FDA of an interruption or discontinuance in production.

Among other provisions, under FDASIA, the Secretary of Health and Human Services is required to: (1) maintain a publicly available, up-to-date drug shortage list; (2) establish a task force to implement a strategic plan to prevent and mitigate drug shortages; and (3) submit annual reports to Congress including relating actions taken by the agency.

FDASIA also required GAO to "examine the cause of drug shortages and formulate recommendations on how to prevent or alleviate such shortages."

Last October, FDA issued its "Strategic Plan for Preventing and Mitigating Drug Shortages." Further, we now have FDA's first annual report on drug shortages, though it only covers the first three quarters of 2013.

And, today, GAO released its final report pursuant to FDASIA.

While drug shortages continue to plague our healthcare system, statistics do indicate progress on some fronts. I am pleased to see that legislation coming out of this Subcommittee has had a positive impact.

I would like to welcome our witnesses, Marcia Crosse, Health Care Director at GAO, and Douglas Throckmorton, Deputy Director of Regulatory Programs at the FDA. I would particularly like to thank GAO for their comprehensive report and the time they have spent with my staff on this issue.

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